



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,948	12/11/2003	Victor Stevens	STEVENS 01.01 DIV	7271
43755	7590	11/30/2006		
DALE F. REGELMAN LAW OFFICE OF DALE F. REGELMAN, P.C. 4231 SOUTH FREMONT AVENUE TUCSON, AZ 85714			EXAMINER RAMACHANDRAN, UMAMAHESWARI	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/732,948	STEVENS, VICTOR	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The restriction is withdrawn as claim 20 is treated as a method claim. Claims 1-20 are pending.

Objection to Specification

The disclosure is objected to because of the following informalities: The sentence is not clear in lines 5-6, p5 of the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 103

Claims 1-6, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tetreault (CA 2,112,754) in view of Kiresuto (JP 54044611) and further in view of Sandborn (U.S. 4,575,515).

Tetreault teaches a method of using a suitable mixture of DMSO and hydrogen peroxide for cancer remedy. The reference also teaches the penetrating ability of DMSO (see Abstract). The reference does not teach a composition comprising second polar compound in the method of treatment of painful joint, muscle etc in the.

Kiresuto teaches that methylsulfonylmethane, a metabolite of DMSO is obtained by oxidizing DMSO (see Abstract). The reference does not teach the amount of the polar compounds and a composition comprising polyols in the method of treatment of painful joint, muscle etc.

Sandborn teaches a pharmaceutical solution comprising 40-85% DMSO by weight along with glycerol (col. 2 lines 18-25). The reference teaches that DMSO of various strengths after topical applications reduces inflammation and pain in a wide range of conditions by penetrating into the skin (col. 1 lines 11-20) and glycerol for the

Art Unit: 1617

retention of moisture in the skin. Claim 5 is addressed here as the first and the second polyol compound can be glycerol.

It would have been obvious to one skilled in the art to at the time the claimed invention was made to combine all of the above teachings for the treatment of painful joint, muscle, tendon etc. The motivation to do so is derived from Sandborn. Sandborn teaches the ability of DMSO to penetrate the skin and other membranes that has facilitated its use as vehicle for the administration of drugs through topical application and the retention of moisture in the skin by glycerol.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tetreault (CA 2,112,754) in view of Kiresuto (JP 54044611) and further in view of Sandborn (U.S. 4,575,515) as applied to claims 1-6, 8, 9 above and further in view of Vanden Berghe et al (WO 98/52576).

The teachings of Tetreault (CA 2,112,754) in view of Kiresuto (JP 54044611) and further in view of Sandborn (U.S. 4,575,515) have been discussed in the 103(a) rejection set forth above.

The references does not teach a method of treatment of painful joint, muscle, tendon etc comprising administering a composition with a second polyol such as glucosamine.

Vanden Berghe et al. teaches a topical medicament of glucosmine and glycerol in the use of treatment of local pain that results from tendonitis, rheumatism, arthritis etc (p5, formulation 2, example 2).

Art Unit: 1617

It would have been obvious to one skilled in the art to at the time the claimed invention was made to combine all of the above teachings for the treatment of painful joint, muscle, tendon etc. The motivation to do so is derived from Vanden Berghe et al. The reference teaches that the topical application of glucosamine alleviates pain in a very short delay of time by single treatment and also has less undesired side effects compared to the oral pain killers taken over a prolonged period of time.

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tetreault (CA 2,112,754) in view of Kiresuto (JP 54044611), further in view of Sandborn (U.S. 4,575,515) and further in view of Vanden Berghe et al (WO 98/52576) as applied to claims 1-9 above and in view of Hood (U.S. 6,103,241) and further in view of Tschollar et al.(WO 98/02182).

The teachings of Tetreault (CA 2,112,754) in view of Kiresuto (JP 54044611), further in view of Sandborn (U.S. 4,575,515) and further in view of Vanden Berghe et al (WO 98/52576) have been discussed in the 103(a) rejection set forth above.

The references do not teach a method of treatment of painful joint, muscle, tendon etc comprising administering a composition with terpenoids.

Hood teaches a method of reducing pain comprising administering topically an essential oil that comprises alpha-pinene, and 1,8-cineole addressing claims 11-13, 16-18 and 19. The reference does not teach a terpenoid alcohol compound.

Tschollar et al. teaches a pharmaceutical composition comprising non-steroidal anti- inflammatory drugs with terpenoid compounds such as cineol, menthol, 3-carene for the treatment of osteoarthritis, rheumatoid arthritis, acute musculoskeletal pain,

Art Unit: 1617

muscular pain, back pain, shoulder pain etc (claim 10, p 6 lines 6-10). The reference teaches that a combination therapy with NSAID and terpenoid has enhanced effect and has fewer side effects than when treated with NSAID alone (p1 lines 8-16). This addresses claims 14, 15 and 20.

It would have been obvious to one skill in the art to at the time the claimed invention was made to combine all of the above teachings along with Hood and Tschollar et al. for the treatment of painful joint, muscle, tendon etc. The motivation to do is provided by Tschollar et al and Hood et al. Hood et al. teaches that the essential oil comprising terpenoids has the ability to reduce pain caused by muscle and tendon strain and has also been found to reduce pain from gout, headache, and bites. Tschollar et al teaches the combination therapy of NSAID and terpenoid with enhanced effects and with less side effects when treated with NSAID alone (p1 lines 8-16). Hence it is obvious for one skilled in the art to combine an oxidizing agent, polar compounds and terpenoids for the treatment of pain as the prior art teaches the usefulness of these compounds in the treatment of arthritis, muscular pain, back pain, osteoarthritis etc.

The examiner further respectfully points out the following from MPEP 2144.06: "It is **prima facie obvious** to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their, having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,-1072 (CCPA 1980).

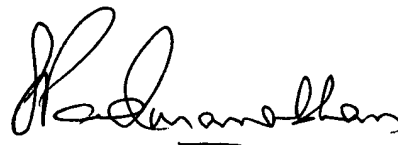
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER